

Quality Control Materials for use with BioFire® FilmArray® Panels

Introduction

The Clinical Laboratory Improvement Amendments (CLIA), passed in 1988, establishes quality standards for all laboratory testing to ensure the accuracy and reliability of patient test results, regardless of where the test is performed. CLIA regulations require a laboratory to have quality control (QC) procedures to monitor the accuracy and precision of the complete testing process.

This document provides a listing of QC materials that have been tested at BioFire and are compatible with the BioFire Panels indicated. The information in this document is meant to be a guideline and may not be inclusive.

For guidelines to assist your laboratory in developing an individualized quality control plan for BioFire® FilmArray® Systems, please refer to the Example Individualized Quality Control Plan (IQCP) Risk Analysis for the following panels:

- BioFire® FilmArray® Blood Culture Identification (BCID) Panel-FLM1-PRT-0217
- BioFire® Blood Culture Identification 2 (BCID2) Panel –BFR0000-6645
- BioFire® FilmArray® Gastrointestinal (GI) Panel-FLM1-PRT-0218
- BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel-FLM1-PRT-0219
- BioFire® FilmArray® Pneumonia Panel-FLM2-PRT-0313
- BioFire® FilmArray® Respiratory Panel (RP)-BFR0000-8660
- BioFire® FilmArray® Respiratory Panel EZ (RP EZ)- BFR0000-8660
- BioFire® FilmArray® Respiratory Panel 2 (RP2)- BFR0000-8660
- BioFire® FilmArray® Respiratory Panel 2 *plus* (RP2*plus*) -BFR0000-8660
- BioFire® Respiratory Panel 2.1 (RP2.1)-BFR0000-8660
- BioFire® Respiratory Panel 2.1 *plus* (RP2.1*plus*)- BFR000-8660
- BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ)-BFR000-8660



Note: The QC materials listed are appropriate for use with the panel described and may not be compatible with other BioFire Panels.

1. Quality Control Resources

Table 1. QC Materials for BioFire BCID Panel

BioFire BCID Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® BCID Control Panel	M235
Microbiologics	Blood Culture Identification (BCID) Control Panel (Inactivated)	8215

Table 2. QC Materials for BioFire BCID2 Panel

BioFire BCID2 Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® BCID2 Control Panel*	M416

*For in vitro Diagnostic Use; an FDA cleared class II assayed control

Table 3. QC Materials for BioFire GI Panel

BioFire GI Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® GI Control Panel	M238
ZeptoMetrix Corporation	NATtrol™ GI Controls	NATGIC-BIO

Table 4. QC Materials for BioFire ME Panel

BioFire ME Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	INTROL® ME Control Panel	M262
ZeptoMetrix Corporation	NATtrol™ Meningitis/Encephalitis (ME) Controls	NATMEC-BIO

Table 5. QC Materials for BioFire Pneumonia Panel and Pneumonia *plus* Panel

BioFire Pneumonia Panel and Pneumonia <i>plus</i> Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® Pneumonia/ Pneumonia <i>plus</i> Control*§	M340

*For in vitro Diagnostic Use; an FDA cleared class II assayed control

§ Control contains MERS-CoV2 recombinant material

Table 6. QC Materials for BioFire RP

BioFire RP		
Vendor	Product Name	Part Number
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS/ RPNEG
Maine Molecular Quality Controls, Inc.	FilmArray® RP Control Panel	M210
Microbiologics	Respiratory (21 Targets) Control Panel	8217
ZeptoMetrix Corporation	NATtrol™ RP Multimarker Controls	MDZ001

Table 7. QC Materials for BioFire RP EZ

BioFire RP EZ		
Vendor	Product Name	Part Number
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS/ RPNEG
Maine Molecular Quality Controls, Inc.	FilmArray® RP EZ Control Panel*	M265
Microbiologics	Respiratory (21 Targets) Control Panel	8217
ZeptoMetrix Corporation	NATtrol™ RP Multimarker Controls	MDZ001

*For in vitro Diagnostic Use; an FDA cleared class II assayed control

Table 8. QC Materials for BioFire RP2 and RP2plus

BioFire RP1 and RP2plus		
Vendor	Product Name	Part Number
Exact Diagnostics	RP Positive Run Control [§] / RP Negative Run Control	RPPOS/ RPNEG
Maine Molecular Quality Controls, Inc	FilmArray® RP2/RP2plus Control Panel [§]	M315
Microbiologics	Respiratory (21 Targets) Control Panel	8217
ZeptoMetrix Corporation	NATtrol™ Respiratory Panel 2 (RP2) Controls	NATRPC2-BIO

* For in vitro Diagnostic Use; an FDA cleared class II assayed control

[§] Control contains MERS-CoV2 recombinant material

Table 9. QC Materials for BioFire RP2.1, RP2.1 plus, and RP2.1-EZ

BioFire RP2.1, RP2.1 plus, and RP2.1-EZ		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	BioFire RP2.1/RP2.1plus Control Panel	M441

* Quality control options are discussed more thoroughly in *External Control Material Options for BioFire® Respiratory Panel 2.1 (RP2.1)* BFR000-8900

Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the BioFire Technical Support team for assistance.

BioFire Technical Support
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